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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,400

03/12/2004

Nobuaki Mihara

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BUCHANAN, INGERSOLL & ROONEY PC  
POST OFFICE BOX 1404  
ALEXANDRIA, VA 22313-1404

EXAMINER

MCCORKLE, MELISSA A

ART UNIT

PAPER NUMBER

3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/798,400

Applicant(s)

MIHARA ET AL.

Examiner

Melissa A. McCorkle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/01/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

It appears that claim 17 is supposed to be dependent on claim 11, not claim 1, since claim 1 already has a dependent claim identical to claim 17. If this is the case, appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ha et al (6,159,195). Ha discloses the device substantially as claimed.

3. Ha discloses a catheter 110 for penetrating a stenotic lesion in a lumen in a human body, including a linear wire 120, and a tubular body placed on a distal end side of the wire and allowing a guide wire to be inserted through its hollow portion; wherein said wire is metal and has a solid cross section and a covering layer composed of a resin material covering an outside of the metal wire [col 5 lines 65-67], in which the wire has a surface layer composed of a hydrophilic material covering an outer surface of the wire [col 5 line 40]; or in which the tubular body includes a plurality of markers each having a visualization property 127 arranged in a longitudinal direction; in which the tubular body has an inner layer positioned on an inner circumferential side, an outer layer formed on an outer circumferential side of the inner layer, and a reinforcing body [col 7 lines

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40-55] placed between the inner layer and the outer layer; or further including an operation portion 222 places on a proximal end side of the wire, in which the operation portion can be adjusted and fixed for its position with respect to the wire, in which the operation portion is adhered to the wire; or in which a center of the tubular body is decentered with respect to the center of the wire; or in which the wire is connected to the tubular body under a condition that a distal end portion of the wire partially overlaps with a proximal end portion of the tubular body [fig 5, 7, 9, 11, 14].

4. Ha discloses a catheter for penetrating a stenotic lesion in a lumen in a human body, the catheter 110 comprising a linear wire 120 having a distal end, a tubular body having a distal end and a hollow portion adapted to receive a guide wire, the tubular body being secured to the wire so that the distal end of the tubular body is always located distally beyond the distal end of the wire; and wherein the wire is metal and has a solid cross section and a covering layer composed of a resin material covering an outside of the metal wire [col 5 lines 65-67]; further comprising a coupling member 222 which fixes the wire to the tubular body, wherein the coupling member fixes together portions of the wire and the tubular body that overlap one another; or in which the wire has a surface layer composed of a hydrophilic material on the covering layer; wherein the tubular body includes a plurality of markers each having a visualization property 127 arranged in a longitudinal direction; wherein the tubular body comprises an inner layer positioned on an inner circumferential side, an outer layer formed on an outer circumferential side of the inner layer, and a reinforcing body [col 7 lines

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40-55] between the inner layer and the outer layer, further comprising an operation portion at a proximal end side of the wire; wherein the operation portion is adjustable relative to the wire to be fixed at a desired position with respect to the wire; or wherein the operation portion is adhered to the wire; in which the tubular body and the wire are not coaxially disposed relative to each other; wherein the wire is secured to the tubular body such that a distal end portion of the wire partially overlaps a proximal end portion of the tubular body in an axial direction [column 5-7, fig 5, 7, 9, 11, 14].

### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. de Toledo et al (6,248,100) discloses a Drainage Catheter Delivery System; Ciamacco Jr. et al (5,772,642) discloses a Closed End Catheter; Samson (5,702,373) discloses a Composite Super-Elastic Alloy Braid Reinforced Catheter, Sirhan (5,709,658) discloses a Rapid Exchange Type Over-the-Wire Catheter.

### **Contacts**

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9:00am - 5:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melissa A McCorkle  
Examiner  
Art Unit 3763

MAM  
03/02/2007



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